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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/426,038 10/25/99 VIND J 5579.210-US **EXAMINER** HM22/1107 STEVE T ZELSON ESQ PONNALURI, P NOVO NORDISK OF NORTH AMERICA INC **ART UNIT** PAPER NUMBER 405 LEXINGTON AVENUE **SUITE 6400** 1627 NEW YORK NY 10174-6401 **DATE MAILED:** 11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Application No. 09/426,038

Applic (s)

P. Ponnaluri

Office Action Summary

Examiner

Group Art Unit

1627

Vind

Restriction purposes only Responsive to communication(s) filed on Oct 25, 1999	
☐ This action is <b>FINAL</b> .	
☐ Since this application is in condition for allowance except for in accordance with the practice under <i>Ex parte Quayle</i> , 1935	· ·
A shortened statutory period for response to this action is set to is longer, from the mailing date of this communication. Failure to application to become abandoned. (35 U.S.C. § 133). Extension 37 CFR 1.136(a).	o respond within the period for response will cause the
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
Claim(s)	is/are allowed.
Claim(s)	is/are rejected.
Claim(s)	
	are subject to restriction or election requirement.
Application Papers  See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  The drawing(s) filed on is/are objected to by the Examiner.  The proposed drawing correction, filed on is approved disapproved.  The specification is objected to by the Examiner.  The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. § 119  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  All Some* None of the CERTIFIED copies of the priority documents have been received.  The cecived in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  *Certified copies not received: Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
	under 35 0.5.C. ¥ 119(e).
Attachment(s)  Notice of References Cited, PTO-892  Information Disclosure Statement(s), PTO-1449, Paper No.  Interview Summary, PTO-413  Notice of Draftsperson's Patent Drawing Review, PTO-948  Notice of Informal Patent Application, PTO-152  PTO restriction for were sheet	
SEE OFFICE ACTION ON TH	IE FOLLOWING DACES

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1. This application is a continuation in part of application serial number 09/186,665.

2. The preliminary amendment filed on 10/25/99 has been fully considered and entered into

the application.

3. Claims 23-26 have been canceled by the amendment filed on 10/25/99, and claims 1-22

and 27-29 are currently pending in this application.

Please Note: In an effort to enhance communication with our customers and reduce processing

time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-

4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage

your participation in this Pilot program. If you have any questions or suggestions please contact

Jyothsna Venkat, Ph.D., Supervisory Patent Examiner at jyothsna.venkat@uspto.gov or 703-308-

2439. Thank you in advance for allowing us to enhance our customer service. Please limit the

use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, drawn to a method of constructing and selecting or screening a

library of polynucleotide sequences of interest in filamentous fungal cells, classified

in class 435, subclass 6.

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II. Claims 22-27, drawn to a method of constructing and screening or selecting a library of polymucleotide sequence of interest in filamentous fungal cells, classified in class 435, subclass 6.

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- III. Claims 28-29, drawn to a library of polynucleotide sequences of interest which library comprises filamentous fungal cells transformed with a population of DNA vectors, classified in class 536, subclass 25.6.
- Inventions are distinct, each from the other because of the following reasons: a)

  Inventions group I and group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of group I are drawn to a method of constructing and selecting a library of polynucleotides, using fungal markers and fungal replication initiating sequence; which is different from the group II method which uses bacterial or yeast selection markers and bacterial or yeast replication initiating sequences. Thus restriction among the groups is proper.
- b) Inventions of group II and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the group II are drawn to a method of making and selecting a library of nucleotides using bacterial or yeast selection markers and bacterial or yeast replication

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initiating sequences; and group III inventions are drawn to a library of polynucleotide sequences of interest which library comprises filamentous fungal cells transformed with a population of DNA vectors. Thus restriction among the groups is proper.

- 6. Inventions of group I and group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the library of polynucleotide sequences of interest comprising fungal cells can be made using entirely different method from group I (i.e, see group II).
- 7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 8. This application contains claims directed to the following patentably distinct species of the claimed invention:
- A) If group I is elected applicants are requested to elect a single species from each of the following groups:
  - a) Replication initiating sequences, SEQ ID NO: 1 or SEQ ID NO: 2;
- b) polynucleotide sequences are prepared by: random mutagenesis or naturally occurring allelic variations of parent nucleic acids;

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c) polynucleotide sequence encodes: a polypeptide; or control sequence; or part of polypeptide; or part of control sequence;

- d) If in c) polypeptide is elected applicants are requested to elect a single species from: hormone; an enzyme; a receptor; a portion of receptor; an antibody; a portion of an antibody; a reporter; a regulatory protein;
- e) If in d) an enzyme is elected applicants are requested to elect a single type of enzyme from claim 5;
- f) if in d) an enzyme is elected applicants are further requested to elect a single type of enzyme from claim 6;
  - g) applicants are requested to elect a single type of control sequence from claim 7;
- h) if in g) a promoter is elected applicants are requested to elect one type of promoter from claim 8;
  - I) applicants are requested to elect a selective marker from claim 9;
- j) if in I) a prototophy to auxotrophs as selective marker is elected, applicants are requested to elect one single type of metabolic pathways from claim 10;
- k) applicants are requested to elect a single type of gene for selective marker from claim 11;
- i) applicants are requested to elect a single type of replication initiating sequence from group a), b), c) or d);
  - m) applicants are requested to elect nucleic acid sequence ID No: 1 or SEQ ID NO: 2;

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n) applicants are requested to elect a single type of modification of the parent polynucleotide sequences from claim 18;

o) applicants are requested to elect a single type of fungal cell from claims 20 and 21.

The species are distinct from each other because they are structurally and functionally different from each other and do not require the other for ultimate use, the species election for examination purposes as indicated is proper.

B) If group II is elected, applicants are requested to elect a) either bacterial or yeast cells; and b) selective markers (either bacterial or yeast cells); and c) bacterial or yeast replication initiating sequence

The species are distinct from each other because they are structurally and functionally different from each other and do not require the other for ultimate use, the species election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 14-17, and 28-29 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 10. Applicant is required to reply to this restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

Any inquiry concerning this communication should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703)308-2439. The fax number for this group is (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

P. Ponnaluri

Patent Examiner

Technology center 1600

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06 November 2000



## RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:		
FROM/ATTORNEY	:	
FIRM:		
PAGES, INCLUDING COVERSHEET:		
PHONE NUMBER:		
TO EXAMINER:	P. Ponnaluri	
ART UNIT:	1627	
SERIAL NUMBER:	09/426,038	
FAX/TELECOPIER NUMBER: (703) 308-4315		
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COMMENTS:		

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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